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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/715,965	11/17/00	DENHOLM E	IT 106

HM22/0813

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EXAMINER	
MELLER, M	
ART UNIT	**PAPER NUMBER**
1651	6
DATE MAILED:	08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/715,965	Applicant(s) DENHOLM ET AL.	
	Examiner Michael V. Meller	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) 12-18 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method of using an enzyme to modulate angiogenesis, classified in class 514, subclass 908, for example.

II. Claims 12-18, drawn to a formulation comprising the enzyme and a pharmaceutically acceptable carrier, classified in class 435, subclass 232, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially distinct process such as treating AIDS.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the many different enzymes and disorders claimed .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Patrea Pabst on 7/26/2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11, the disorder cancer and the enzyme, chondroitinase AC. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-11 are being examined only in so far as they are drawn to the elected species, cancer as the disorder and chondroitinase AC as the enzyme.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite since "modulate angiogenesis" is not clear. What does applicant mean by "modulate" ? This term has a very broad meaning and is relative and subjective. The metes and bounds of this claim are not clear on the record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi.

Takeuchi teaches that mice injected subcutaneously with solid Ehrlich ascites tumors are also injected subcutaneously with chondroitinase AC, see abstract, page 115-116, under "Materials and Methods", page 118, left column, first full paragraph, and the "Discussion". Takeuchi also teaches that the growth of the tumor cells was decreased when the chondroitinase AC was administered. The fact that the mice are injected with Ehrlich ascites tumor cells gives them cancer and then they are treated with the chondroitinase AC. Ehrlich ascites tumor cells are known cancer cells as is evidenced by JP 51075042, relying on abstract only.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeuchi in view of JP 51075042 (relying on abstract only).

Takeuchi teaches that mice injected subcutaneously with solid Ehrlich ascites tumors are also injected subcutaneously with chondroitinase AC, see abstract, page 115-116, under "Materials and Methods", page 118, left column, first full paragraph, and the "Discussion". Takeuchi also teaches that the growth of the tumor cells was decreased when the chondroitinase AC was administered. The fact that the mice are injected with Ehrlich ascites tumor cells gives them cancer and then they are treated with the chondroitinase AC. Ehrlich ascites tumor cells are known cancer cells as is evidenced by JP 51075042, see abstract.

Takeuchi does not teach that the chondroitinase AC is administered topically, locally or by controlled and/or sustained release formulation.

To use different routes of administration would have been obvious to one of ordinary skill in the art since different routes of administration are well known in the art and one would want to optimize the most ways of administering the enzyme composition to a patient in need of it.

To formulate a controlled or sustained release formulation also would have been obvious since one routinely would want to deliver the medication at different times or to allow it to go into the body slower.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Takeuchi and JP 51075042 (relying on abstract only).

Brown teaches that chondroitinase AC can be injected into humans for the treatment of intervertebral disc displacement. The references also teaches that the enzyme can also be used to treat tumors, see col. 4, lines 9-53.

Brown does not teach that the tumor is necessarily cancerous or that it is a solid tumor. Further Brown does not teach the chondroitinase AC is administered topically, locally or by controlled and/or sustained release formulation.

It would have been obvious for one of ordinary skill in the art to administer the enzyme to a cancerous tumor since Takeuchi teaches that chondoitinase AC is beneficially used to treat solid Ehrlich ascites tumors, see abstract, page 115-116, under "Materials and Methods", page 118, left column, first full paragraph, and the "Discussion". Since Ehrlich ascites tumors are known to be cancerous tumors as evidenced by JP 51075042, then it would have been obvious to administer such an enzyme to a cancerous tumor. Further, it would have been obvious to administer the enzyme to a solid tumor since Takeuchi's tumor is solid.

To use different routes of administration would have been obvious to one of ordinary skill in the art since different routes of administration are well known in the art

and one would want to optimize the most ways of administering the enzyme composition to a patient in need of it.

To formulate a controlled or sustained release formulation also would have been obvious since one routinely would want to deliver the medication at different times or to allow it to go into the body slower.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 10:30am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM

August 10, 2001

Michael Meller

Patent Examiner

Art Unit 1651